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EXAMINER				
SZPIRA, JULIE ANN				
ART UNIT		PAPER NUMBER		
3731				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/687,108

**Applicant(s)**

KAISER ET AL.

**Examiner**

JULIE A. SZPIRA

**Art Unit**

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 May 2011.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15, 16, 19-21, 24-27, 32-35, 37-41, 43 and 46 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 15, 16, 19-21, 24-27, 32-35, 37-41, 43 and 46 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-946)  
3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Receipt is acknowledged of applicant's amendment filed 5/2/2011. Claims 15, 16, 19-21, 24-27, 32-35, 37-41, 43 and 46 are pending and an action on the merits is as follows.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. **Claims 15, 16, 19-21, 24-26, 41, 43 and 46** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scarborough et al. (US 5,632,747)** in view of **Lin (US 6,808,182)**, further in view of **Kageyama et al. (US 4,856,693)**.

**Regarding claim 15**, Scarborough et al. discloses an apparatus for harvesting and implanting a bone core, comprising:

a collet assembly (310) including a selectively engageable mechanism and defining an internal bore;

a harvester (40) to selectively engage said selectively engageable mechanism and to be disposed within said internal bore, said harvester defining a harvester throughbore (figure 20);

a first graspable assembly (20) and a separate second graspable assembly (Figure 19) to selectively engage said collet and each defining a graspable assembly

bore (28) that is generally aligned with said harvester bore when said second assembly separately and electively engages said collet assembly;

wherein said first graspable assembly is a drill motor (20) and a second graspable assembly is a handle (figure 19) wherein said drill motor individually selectively engages said collet assembly (column 4, lines 10-14, wherein said selectively engageable mechanism includes a generally quick-release mechanism (where the components are all threadably received, thus comprising a generally-quick-release mechanism) wherein said harvester is engageable and disengageable from said selectively engageable mechanism with pressure from the user (column 7, lines 34-40), but fails to disclose the specific structure of the collet assembly wherein the assembly has a throughbore.

However, Lin teaches a collet assembly having a sleeve (3) defining a bore (311), a collar (2) disposed within said sleeve bore, and a compression spring (33) within said sleeve bore disposed between the collar and the sleeve providing a biasing force that biases the collar to a first position (column 2, lines 18-31), a pin (34) extending from said collar to engage a proximal pin engaging depression in an end wall of said harvester such that as a torque is applied to said collet assembly the torque is transferred to said harvester (column 2, lines 43-51; the pin engages an aperture in the harvester and locks the harvester and the collet assembly together), wherein said collar is slidable within said sleeve bore when acted upon by said harvester (when the sleeve is held stationary, force applied to said harvester would compress the spring, thus moving the collar within the sleeve).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the collet assembly described by Lin in combination with a harvesting device since the collet assembly of Lin allow for a quick release and installation of a cutting (harvesting) tool (column 1, lines 28-30).

Kageyama et al. teaches a collet assembly for holding a tubular item therein the collet comprises a sleeve (1) and a collar (2) a compression spring (3) to provide a biasing force on the collar, wherein the sleeve and collar comprises a throughbore (Figure 1).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a throughbore in the collar and the sleeve to allow for an item located therein to pass completely through the device unobstructed, as would be necessary and convenient for a harvesting tool.

**Regarding claim 16**, Scarborough et al. as modified above discloses the apparatus as stated above further comprising:

a plunger (324) moveable within said graspable assembly bore and said harvester bore;

wherein said plunger is operable with said harvester bore during a harvesting of the bone core;

wherein said collet is disengageable from both the first and second graspable assembly and said plunger is operable to remove the bone core from said harvester (figures 22 and 23), but fails to specifically disclose the collar, sleeve and harvester throughbores are operable to be substantially co-axial.

However, Kageyama et al. teaches a coaxial collet assembly where the throughbores of the collar and sleeve are coaxial, as well as the inserted bar member or harvester (Figure 1).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to arrange the throughbores coaxially to allow for a piece of harvested material to pass therethrough and be removed after the procedure has been completed.

**Regarding claim 19**, Scarborough et al. disclose the apparatus as stated above wherein said harvester includes a collet engaging end and a harvesting end (figure 19);

wherein said harvesting end includes a sharpened portion to cut a selected portion of a bone to harvest the bone core;

wherein said harvester is operable to collect the bone core within said harvester bore (column 7, lines 19-21; figure 22).

**Regarding claim 20**, Scarborough et al. disclose the apparatus as stated above wherein said sharpened end includes at least one of a sawtooth and a generally planar edge (part 40, figures 20-22).

**Regarding claim 21**, Scarborough et al. disclose the apparatus as stated above wherein the bone core may be removed from either of said collet engaging end and said harvesting end (figures 22 and 23; column 7, lines 26-33).

**Regarding claim 24**, Scarborough et al. disclose the apparatus as stated above wherein the bone core is collectible within said harvester bore and said plunger (324) is operable to remove the bone core from said harvester bore (figure 23).

**Regarding claim 25**, Scarborough et al. disclose the apparatus as stated above wherein said plunger (324) is able to push the selected bone portion into a selected position from the harvester substantially directly from the harvester (figure 23).

**Regarding claim 26**, Scarborough et al. disclose the apparatus as stated above wherein said harvester bore (40) is substantially equal in at least one dimension throughout (Figs 19-22).

**Regarding claim 41**, Scarborough et al. disclose an instrument forming a selected core of a bone, comprising:

a harvesting member (40) operable to be driven into a selected portion of bone, said harvesting member having a bearing aperture; said harvesting member defines a harvesting cannula including a dimension substantially equal throughout a length of said harvesting member; and

a graspable portion (20) extending from said harvesting member such that said harvesting member can be positioned relative to a selected portion of bone for forming the bone core; and

a collet assembly having a member cannula (310) and a bearing member at least partially positioned within said internal sleeve bore (when the device is assembled, the bearing member is located inside the sleeve bore) while the bearing member remains external to the member cannula (Figure 19); but fails to disclose the specific structure of the collet assembly.

However, Lin teaches a collet assembly having a sleeve (3) defining a bore (311), a collar (2) disposed within said sleeve bore, and a compression spring (33)

within said sleeve bore disposed between the collar and the sleeve providing a biasing force that biases the collar to a first position (column 2, lines 18-31), a bearing member (34) extending from said collar to engage a bearing aperture in an end wall of said harvester to hold said collar in a selected position and hold said harvesting member relative to said graspable portion (column 2, lines 43-51; the pin engages an aperture in the harvester and locks the harvester and the collet assembly together).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the collet assembly described by Lin in combination with a harvesting device since the collet assembly of Lin allow for a quick release and installation of a cutting (harvesting) tool (column 1, lines 28-30).

Kageyama et al. teaches a collet assembly for holding a tubular item therein the collet comprises a sleeve (1) and a collar (2) a compression spring (3) to provide a biasing force on the collar, wherein the sleeve and collar comprises a throughbore (Figure 1).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a throughbore in the collar and the sleeve to allow for an item located therein to pass completely through the device unobstructed (such as a plunger), as would be necessary and convenient for a harvesting tool.

**Regarding claim 43,** Scarborough et al. disclose an instrument further comprising: a plunger member (324); wherein said plunger member is operable to be moved through said internal cannula to remove the selected bone core from the cannula



(column 7, lines 35-39), but fails to disclose the plunger moving through the cannulas simultaneously.

However, Kageyama et al. teaches a plurality of cannula members (inner and outer sleeves), and a member that functions as a plunger (8) that can pass through the cannula members simultaneously.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to allow the plunger to pass through the cannula members simultaneously to expedite the bone core removable process, as well as reduce the number of parts the device needs to work effectively.

**Regarding claim 46**, Scarborough et al. disclose the apparatus as stated above wherein said handle (20) is a driveable handle that is operable to be struck to drive said generally planar edge of said harvesting member substantially axially into a surface and maintain the bone core within said harvesting member (figure 22);

wherein said drill motor is operable to rotate said harvesting member with said sawtooth into a surface and maintain the bone core within said harvesting member (column 4, lines 10-15; column 5, lines 13-24).

3. **Claims 35 and 37-40** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scarborough et al. (US 5,632,747)** in view of **Lin (US 6,808,182)**.

**Regarding claim 35**, Scarborough et al. disclose an instrument for harvesting a selected bone core, comprising:

a graspable member (20) operable to be grasped by a user, said graspable member (20) includes both an impact handle and a drill motor, wherein both handle and motor are selectively engaged with said connecting member (figure 19).

a harvest member (40) operable with said graspable member to harvest the selected bone core;

a connecting assembly including a connecting member (310) having a connecting member cannula (312) and a spring biasing member (330) and a bearing member (316) positioned within a sleeve, said connecting assembly operable to selectively interconnect said graspable member and said harvest member;

wherein said bearing member (316) engages a bearing aperture of the harvest member in a quick release manner (figure 19) to selectively hold the harvest member relative the graspable member and said bearing member remaining substantially external to said connecting member cannula (the bearing member extends proximally from the cannula; Figure 19);

wherein the spring biasing member compresses between the harvest member and a wall within the sleeve when bearing member is engaged to the harvest member (figure 22), but fails to disclose the connecting member being quick release.

Lin teaches a quick release collet assembly (Abstract).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the collet assembly described by Lin in combination with a harvesting device since the collet assembly of Lin allow for a quick release and installation of a cutting (harvesting) tool (column 1, lines 28-30).

**Regarding claim 37**, Scarborough et al. disclose an instrument wherein said harvest member (40) includes a cannula operable to be aligned with said connecting member cannula including a cutting end including at least one of a sharpened edge and a saw tooth.

**Regarding claim 38**, Scarborough et al. disclose an instrument wherein said connecting member (316 part of 310) couples with said harvest member; wherein said harvest member can be coupled and uncoupled from said connecting member with a substantially axial motion alone.

**Regarding claim 39**, Scarborough et al. disclose an instrument wherein said harvest member is removably couplable to said a connecting member (column 6, lines 46-47 and column 7, lines 34-40).

**Regarding claim 40**, Scarborough et al. disclose an instrument wherein said graspable member is removably couplable to said a connecting member (part 314 of 310; column 6, lines 45-46).

4. **Claims 27 and 32-34** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scarborough et al. (US 5,632,747)** in view of **Bobic et al. (US 5,919,196)**, further in view of **Lin (US 6,808,182)** and **Kageyama et al. (US 4,856,693)**.

**Regarding claim 27**, Scarborough et al. disclose a method of harvesting and implanting a bone core, comprising:

interconnecting a harvesting member (40) with a collet member, including operably contacting said harvesting member (40) with a biasing member (330) and providing a biasing force on said harvesting member (column 7, lines 14-24);

interconnecting said collet (310) with a graspable member (20) alternately includes selectively connecting said collet to a drill motor such that said drill motor is able to rotate said collet (column 4, lines 10-14 and column 7, lines 34-40, where selective locking is shown by the selectively coupled members).

driving said harvesting member into a selected bone portion; trapping a selected length of bone within said harvesting member (figure 20), wherein driving said harvesting member includes: rotating said harvesting member with said drill motor (column 2, lines 1-11); and pressing said harvesting member into the selected bone portion to remove the selected length of bone into said harvesting member (column 1, lines 49-64);

removing said selected length of bone from said harvesting member into a selected location (figure 22),

wherein interconnecting said collet with a graspable member includes selectively locking said collet member to a graspable handle (figure 19), but fails to teach striking said graspable member with a mallet, and the collet assembly being quick release.

However, Bobic et al. teaches striking a handle with a mallet to drive a selected end of a member into bone (column 3, lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the invention of Scarborough et al. with the collet taught by Bobic et al. in order to better drive the harvester assembly into the site (column 5, lines 53-55).

Lin teaches a quick release collet assembly (Abstract).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the collet assembly described by Lin in combination with a harvesting device since the collet assembly of Lin allow for a quick release and installation of a cutting (harvesting) tool (column 1, lines 28-30).

Kageyama et al. teaches a plurality of cannula members (inner and outer sleeves), and a means to remove a trapped selected length of material from a throughbore defined at least through said harvesting member (1) and said collet (2).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to allow for a length of bone material to be passed through the throughbores of the collet and the harvesting member to expedite the bone core removable process, without needing to remove the device from the body. A throughbore will allow for a bone core material to be passed completely through the device, from the distal to the proximal end, and thus allows for continuous removal of cored material from the body without causing the coring device to have to removed from body to remove a portion of cored material.

**Regarding claim 32**, Scarborough et al. disclose the method as stated above further comprising:

disposing said harvesting member with said trapped selected length of bone relative to an implant site; and

wherein removing said selected length of bone includes pushing said selected length of bone into the implant site (figure 22; column 7, lines 25-33, where "into" is taken to mean "in the direction of").

**Regarding claim 33**, Scarborough et al. disclose the method as stated above further comprising:

disposing a plunger (324) through at least a portion of said harvesting member (40); wherein removing said selected length of bone includes pushing said selective length of bone from said harvester into the implant site with the plunger (figure 22; column 7, lines 25-33, where "into" is taken to mean "in the direction of").

**Regarding claim 34**, Scarborough et al. disclose the method as stated above wherein the harvesting member (40) includes a first end and a second end, wherein removing said selective length of bone includes removing the selected length of bone from at least one of the first end and the second end (figure 23), but fails to disclose the means for interconnecting said harvesting member with said collet.

However, Lin et al. teaches interconnecting in a quick release manner including connecting a harvesting member (40) over a member cannula and moving a collar within a throughbore of a sleeve against said biasing member (36) to allow a pin (34) extending from said collar to engage a proximal pin engaging depression in an end wall of said harvester and remain exterior to at least said member cannula (column 2, lines

43-51; the pin engages an aperture in the harvester and locks the harvester and the collet assembly together).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the collet assembly described by Lin in combination with a harvesting device since the collet assembly of Lin allow for a quick release and installation of a cutting (harvesting) tool (column 1, lines 28-30).

### ***Response to Arguments***

Applicant's arguments with respect to claims 15, 16, 19-21, 24-27, 32-34 41, 43 and 46 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments regarding claim 35 have been fully considered but they are not persuasive.

The applicant's arguments are based on the assertion that Lin does not disclose a connecting member assembly, including a connecting member cannula. Without conceding that the applicant's assertion is correct, the arguments are not persuasive, as Scarborough et al. teaches the connecting assembly comprising a connecting member cannula and a bearing member remaining substantially external to the connecting member cannula. The combination of the connection assembly disclosed by Scarborough with the quick release teachings of Lin would have been obvious to one having ordinary skill in the art at the time the invention was made, as Scarborough discloses that a bone coring device would advantageously be capable of being separated for cleaning (column 5, lines 8-12), and Lin teaches a quick release element

that allows for the tool bit (the harvesting tool) to be connected or released from the handpiece with relative ease.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Szpira whose telephone number is (571) 270-3866. The examiner can normally be reached on Monday-Friday, 10AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, Tom Hughes, at (571) 272-4357. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to:

TC3700\_Workgroup\_D\_Inquiries@uspto.gov.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. A. S./  
Examiner, Art Unit 3731  
July 31, 2011

/S. Thomas Hughes/  
Supervisory Patent Examiner, Art Unit 3731